

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA**

**IN RE: SOCLEAN, INC., MARKETING,
SALES PRACTICES AND PRODUCTS
LIABILITY LITIGATION**

Master Docket Number: 2:22-mc-152

MDL No. 3021

This Document Relates to:

Albright v. SoClean, Inc., 22-cv-280
Arnouville v. SoClean, Inc., 22-cv-502
Bailey v. SoClean, Inc., 22-cv-494
BeDoit v. SoClean, Inc., 22-cv-528
Blissett v. SoClean, Inc., 22-cv-271
Borland v. SoClean, Inc., 22-cv-293
Brackins et al v. SoClean, Inc., 22-cv-225
Bradley v. SoClean, Inc., 22-cv-439
Brooks v. SoClean, Inc., 22-cv-228
Carlile v. SoClean, Inc., 22-cv-279
Coley v. SoClean, Inc., 22-cv-275
Cupp et al. v. SoClean, Inc., 22-cv-227
Hebert v. SoClean, Inc., 22-cv-231
Hill v. SoClean, Inc., 22-cv-301
Hixon v. SoClean, Inc., 22-cv-504
Hunter-Blank v. SoClean, Inc., 22-cv-233
Ieyoub et. al. v. SoClean, Inc., 22-cv-272
Jenkins v. SoClean, Inc., 22-cv-241
Koumantakis v. SoClean, Inc., 22-cv-335
Landers v. SoClean, Inc., 22-cv-226
Lange v. SoClean, Inc., 22-cv-274
Litman v. SoClean, Inc., 22-cv-501
Morris v. SoClean, Inc., 22-cv-503
Pomianek v. SoClean, Inc., 22-cv-282
Sakalorios v. SoClean, Inc., 22-cv-229
Screen v. SoClean, Inc., 22-cv-273
Seicol v. SoClean, Inc., 22-cv-291
Stahl v. SoClean, Inc., 22-cv-232
Turner v. SoClean, Inc., 22-cv-243
Wharton v. SoClean, Inc., 22-cv-505
Wheeler v. SoClean, Inc., 22-cv-230

FED. R. CIV. P. 26(f) REPORT OF THE PARTIES¹

¹ For clarity, SoClean is a party to these consolidated putative class actions (the “SoClean

- 1. Identification of counsel and unrepresented parties. Set forth the names, addresses, telephone and fax numbers and e-mail addresses of each unrepresented party and of each counsel and identify the parties whom such counsel represent:**

This is a centralized multi-district litigation brought by consumer plaintiffs. Plaintiffs' appointed leadership is set forth in Pretrial Orders Nos. 2 and 5.

Plaintiffs' appointed leadership is set forth in Pretrial Order # 2.

SoClean, Inc. is represented by Proskauer Rose LLP and Marks, O'Neill, O'Brien, Doherty & Kelly, P.C.

- 2. Set forth the general nature of the case (patent, civil rights, anti-trust, class action, etc.):**

Plaintiffs' Position

This case is a procedural consolidation of over 30 putative class actions. In their Consolidated Amended Class Complaint, Plaintiffs intend to seek economic damages related to allegations that SoClean concealed the presence and risk of ozone exposure from SoClean devices used to clean CPAP and BiPAP machines and accessories. Plaintiffs are consumers with SoClean devices which generate ozone (O³) to clean, sanitize, and disinfect CPAP and BiPAP machines and accessories. In February 2020, the FDA issued a press release on its Safety Communication from the same day and stated that ozone gas-based devices "claiming to clean, sanitize or disinfect CPAP machines and accessories" were being "illegally marketed" because they "have not been

Class Actions"), and also is a party to a business litigation brought by SoClean against Philips (the "SoClean-Philips Lawsuit"), all of which have been transferred into MDL 3021 for coordinated discovery and pretrial proceedings as appropriate. This Fed. R. Civ. P. 26(f) Report applies only to SoClean as a party in the SoClean Class Actions, and shall not affect SoClean's rights and obligations as a party in the SoClean-Philips Lawsuit.

FDA cleared or approved for marketing in the U.S.” Additionally, the FDA concluded through testing that “ozone-using disinfection devices generated ambient levels of ozone above limits considered safe for human exposure.” In these class action, Plaintiffs intend to bring state common and statutory law causes of action including warranty, fraud, negligence per se, and consumer protection for economic injury.

Plaintiffs are not asserting claims against SoClean in this action for degradation of recalled Philips CPAP and BiPAP machines. An MDL has been created to represent consumers with recalled Philips machines and this Court has appointed interim leadership to manage the consolidated cases seeking economic losses, medical monitoring, and compensation for personal injuries from all parties who may be responsible for that degradation.

There are currently no individual personal injury mass action cases in MDL 3021 or in the process of being transferred here. Investigations are on-going about potential claims for injuries from ozone exposure.

SoClean’s Position

The SoClean Class Actions are consolidated putative class actions brought by consumer plaintiffs who purchased SoClean devices. The consumer plaintiffs allege SoClean devices emit ambient levels of ozone at a level that exceeds the FDA’s limit for safe human exposure. The consumer plaintiffs point to the FDA’s 2020 Safety Communication about ozone cleaners, but ignore that the communication did not mention SoClean devices, let alone say they are unsafe. The consumer plaintiffs also fail to mention that, earlier this month, the FDA stated that its 2020 Safety Communication about ozone cleaners “did not give device users reason to anticipate . . . that the use of ozone

in ventilated spaces (and utilizing procedures that permitted the circulation of fresh air through the devices) would necessarily present significant risks.”²

In several key respects, the SoClean Class Actions differ from *In re: Philips Recalled CPAP, Bi-Level PAP, and Mechanical Ventilator Products Litigation*, MDL No. 3104 (“MDL 3014”). In 2021, Philips issued an “urgent” medical device recall for certain CPAP, Bi-Level PAP and mechanical ventilator devices (“Recalled Philips Devices”) because, according to Philips, the Recalled Philips Devices’ sound abatement foam “may degrade into particles which may enter the devices’ air pathway and be ingested or inhaled by the user” and “may off-gas certain chemicals.”³ According to Philips, “[t]hese issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment.” *Id.* The consumer plaintiffs in MDL 3014 seek not only economic damages, but also damages for personal injury and medical monitoring. See 26(f) Report in MDL 3014, Dkt. 510, at 1-2.

In contrast, the consumer plaintiffs in the SoClean Class Actions do not allege they have experienced physical harm and have said they will not be asserting claims for personal injury or medical monitoring in the SoClean Class Actions. As noted, the consumer plaintiffs in the SoClean Class Actions merely seek economic damages. And as the consumer plaintiffs stated above, the SoClean Class Actions are *not* about foam degradation or off-gassing, but about whether SoClean devices emit ozone at a level that exceeds the FDA’s limit for safe human exposure.

² <https://www.fda.gov/media/158129/download>

³ https://www.usa.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/en_US/philips-recall-letter-2021-11-16-a-cpap-a-ventilator-recall-letter-us-revised.pdf

Unlike Philips, SoClean has not recalled any of its devices and has not admitted that they pose a safety risk to consumers. SoClean stands by its products' safety. Indeed, SoClean has submitted a de novo application to the FDA and that application was accepted for review. It is pending.

We note these distinctions from MDL 3014 because, as discussed below in Section 5, SoClean intends to move to dismiss the consumer plaintiffs' forthcoming Consolidated Amended Complaint ("CAC"), and to move to stay discovery pending the resolution of its motion to dismiss. SoClean appreciates that the potential for irreparable harm to the plaintiffs in MDL 3014 may have warranted beginning discovery immediately, particularly since Philips warned the Recalled Philips Devices pose an urgent danger to users. But SoClean respectfully submits that there is no such urgency in the SoClean Class Actions given that (1) the consumer plaintiffs merely seek economic damages, (2) there has been no product recall, (3) SoClean has not admitted its products are unsafe and in fact denies such allegations, (4) the FDA is now reviewing SoClean's de novo application, and (5) the FDA recently stated that its 2020 Safety Communication did *not* mean that the use of ozone in ventilated spaces necessarily presents significant risks. Further, SoClean intends to advance in its motion to dismiss multiple independent arguments to dismiss the entire CAC. If SoClean prevails on any of those arguments, there will be no need for any discovery in the SoClean Class Actions. Thus, SoClean respectfully requests that the Court leave in place the existing discovery stay at least until the Court has had the opportunity to consider SoClean's motion to stay.⁴

⁴ The parties to the SoClean Class Actions have agreed on a briefing schedule for the motions, as set forth below in Section 5.

3. **Date Rule 26(f) Conference was held, the identification of those participating therein and the identification of any party who may not yet have been served or entered an appearance as of the date of said Conference:**

The Rule 26(f) conference was held by video-conference on May 5, 11 and 16, 2022.

In attendance for Plaintiffs: Ruth Anne French-Hodson of Sharp Law, Gary Mason of Mason LLP, Gretchen Moore of Strassburger McKenna Gutnick & Gefsky, Sarah Bradshaw of Sharp Law, and Melissa Willett of Mason LLP.

In attendance for SoClean: Michael Hackett, Jeff Warshafsky and Hena Vora of Proskauer Rose LLP and Daniel Bentz of Marks, O'Neill, O'Brien, Doherty & Kelly, P.C.

4. **Date of Rule 16 Initial Scheduling Conference as scheduled by the Court: (Lead Trial Counsel and unrepresented parties shall attend the Rule 16 Initial Scheduling Conference with their calendars in hand for the purpose of scheduling other pre-trial events and procedures, including a Post-Discovery Status Conference; Counsel and unrepresented parties shall attend the Rule 16 Initial Scheduling Conference prepared to discuss the anticipated number of depositions and identities of potential deponents and the anticipated dates by which interrogatories, requests for production of documents and requests for admissions will be served):**

The parties propose that the Rule 16 Initial Scheduling Conference be held on August 31, 2022.

5. **Identify any party who has filed or anticipates filing a dispositive motion pursuant to Fed. R. Civ. P. 12 and the date(s) by which any such anticipated motion may be filed:**

SoClean anticipates filing a Rule 12 motion, and a Rule 26(c) motion to stay discovery pending the resolution of its motion to dismiss the CAC. The Parties have agreed that SoClean may file its Rule 12 motion and Rule 26(c) motion on the same date.

The Parties agree on the following briefing schedule for those motions:

- Plaintiffs file the CAC: July 22, 2022
- SoClean's motion to dismiss: September 12, 2022
- SoClean's motion to stay: September 12, 2022
- Plaintiffs' opposition to SoClean's motion to stay: October 3, 2022
- Plaintiffs' opposition to SoClean's motion to dismiss: November 1, 2022
- SoClean's reply in further support of its motion to dismiss: November 22, 2022

Once Plaintiffs file their CAC, the Parties intend to confer and file a joint motion seeking expanded page limits for the motion to dismiss briefing.

6. Designate the specific Alternative Dispute Resolution (ADR) process the parties have discussed and selected, if any, and specify the anticipated time frame for completion of the ADR process. Set forth any other information the parties wish to communicate to the court regarding the ADR designation:

The Parties agree to the appointment of a mediator, and the Parties propose Retired Judge Diane Welsh as the mediator. The Parties have confirmed that Judge Welsh is available for ADR mediation on August 8 and 10, September 6-8, 12-14, 16, 19, 21, and agree to confer in good faith regarding a potential date for mediation. The Parties believe that the process for ADR should be decided jointly with the mediator.

Plaintiffs have provided SoClean a list of pre-mediation discovery that Plaintiffs believe would be necessary to have in advance to conduct a meaningful mediation.

7. Set forth any change that any party proposes to be made in the timing, form or requirements of Fed. R. Civ. P. Rule 26(a) disclosures, whether such change is opposed by any other party, whether any party has filed a motion seeking such change and whether any such motion has been ruled on by the Court:

- SoClean, Inc.: within 21 days after the filing of the CAC
- Class Representative Plaintiffs: within 21 days after the filing of the CAC

8. **Subjects on which fact discovery may be needed. (By executing this report, no party shall be deemed to (1) have waived the right to conduct discovery on subjects not listed herein or (2) be required to first seek the permission of the Court to conduct discovery with regard to subjects not listed herein):**

Plaintiffs' Position: Plaintiffs believe fact discovery will be needed in the following areas as an initial matter:

- Documents regarding the FDA testing and Safety Communication in February 2020 and any follow-up testing or communications;
- Design changes contemplated or made to the SoClean device and the reasons for the change;
- Commissioned and reviewed studies regarding the safety, risks, and necessary precautions for ozone;
- Marketing material utilized or contemplated over the last decade;
- Authorized third-party retailers;
- Warranty registrations and any changes to those registration forms;
- U.S. sales figures for the class period including annual reports, income statements, and profit & loss reports;
- Organization charts;
- Insurance policies;
- Document retention policies.

SoClean's Position: If discovery takes place, SoClean will seek discovery concerning Plaintiffs' understanding of and reliance on SoClean's advertising, Plaintiffs' alleged purchase and use of SoClean devices, and Plaintiffs' alleged economic damages. SoClean will also seek discovery on all factual allegations raised in the CAC, among other

topics. At this time, without having seen the CAC, it is premature for SoClean to determine what other subjects discovery would need to cover.

9. **Set forth suggested dates for the following (The parties may elect by agreement to schedule a Post-Discovery Status Conference, as identified in Paragraph 12, below, at the conclusion of Fact-Discovery rather than at the conclusion of Expert Discovery. In that event, the parties should provide suggested dates only for the events identified in sub-paragraphs 9.a through 9.e, below. The parties shall provide such information even if dispositive motions pursuant to Fed. R. Civ. P. 12 have been or are anticipated to be filed. If there are dates on which the parties have been unable to agree, set forth the date each party proposes and a brief statement in support of each such party's proposed date. Attach to this report form a proposed Court Order setting forth all dates agreed to below and leaving a blank for the insertion of a date by the Court for any date not agreed to):**

The Parties have agreed to conduct full class certification and merits discovery without phasing. The Parties also generally agree on the overall timing for discovery, but as noted above, the Parties disagree on when discovery should start. Plaintiffs' position is that the "trigger date" for discovery should be the later of when (1) the Court lifts the temporary stay currently in place, or (2) SoClean files its initial disclosures. SoClean's position, as will be set forth in its motion to stay filed contemporaneously with its motion to dismiss, is that discovery should be stayed until the Court decides SoClean's motion to dismiss. Certain dates below are keyed to the Parties' respective "trigger dates" for the start of discovery.

	Consumer Plaintiffs' Proposal	SoClean's Proposal
SoClean Initial Disclosures	21 days after filing of the Consolidated Amended Complaint	
Plaintiffs Initial Disclosures	21 days after filing of the Consolidated Amended Complaint	
Stipulated Protective Order submitted to the Court	No later than June 13, 2022	
ESI Protocol	Parties have agreed to a meet-and-confer timing and schedule to raise disputes to Special Master Katz	
Rule 16 Conference	August 31, 2022	
Production of all material produced to 3B Medical, Inc. in <i>3B Medical, Inc. v. SoClean, Inc.</i> , 19-cv-3545	1 week after trigger date (the parties will work together in advance on any relevancy objections	Relevant materials from the 3B Action to be produced as part of the first rolling production.

(S.D.N.Y.) (“3B Action”)	from SoClean)	SoClean disputes that all materials produced in the 3B Action are relevant here.
Production of FDA file⁵	1 week after trigger date	With the first rolling production. SoClean does not maintain a single file with the requested documents.
Rolling productions start	4 months after trigger date	
Document production substantially complete	8 months after trigger date	
Date by which any additional parties shall be joined and deadline for amending pleadings	The parties will need an order of court to amend pleadings or add new parties.	
Fact discovery complete	13 months after trigger date	
Parties submit proposed case schedule for post-fact discovery proceedings	14 months after trigger date, 1 month after end of fact discovery	
Post-fact discovery status conference pursuant to Local Rule Civil Procedure 16.1(B)(1)(c)	Regular status conference following submission of joint proposed case schedule for post-fact discovery proceedings	

10. **If the parties agree that changes should be made to the limitations on discovery imposed or Local by the Federal Rules of Civil Procedure Rule or that any other limitations should be imposed on discovery, set forth such changes or limitations:**

The service of interrogatories, requests for production of documents and tangible items, notices of depositions and requests for admission shall be governed by the Federal Rules of Civil Procedure and the Local Rules of this Court. Plaintiffs believe that it will be necessary to exceed the 10 deposition and 25 interrogatory limits and will confer in good

⁵ All communications to and from the U.S. Food and Drug Administration related to any SoClean device as well as any internal documentation SoClean is required to collect and maintain for compliance with regulatory obligations to the FDA.

faith in an effort to reach reasonable agreements regarding the number of depositions and interrogatories to be allowed should it become apparent that it is necessary to exceed these limits.

Any deposition requested by another party in either this MDL or MDL No. 3014 will not count toward the number of depositions a party is entitled to, even if that party participates in the deposition for coordination. For clarity, substantive questioning beyond the subject matter of testimony in response to questioning by another party shall count towards a party's deposition limits in the SoClean Class Actions.

11. **Set forth whether the parties have considered the need for special deadlines, procedures or orders of court dealing with discovery of electronically-stored information (electronic discovery), including the need for the preservation of discoverable information and the protection of the right to assert privilege(s) after the production of privileged information and if so, set forth the results of such consideration. In particular, answer the following questions:**

- a. **ESI. Is either party seeking the discovery of ESI in this case?** ☐ **Yes** ☐ **No**

The Parties intend to file a stipulated ESI protocol that will detail how they will facilitate any ESI disputes as they arise.

- b. **Metadata: Will any metadata be relevant in this case?** ☐ **Yes** ☐ **No**

If yes, with respect to what ESI—

The Parties intend to file a stipulated ESI protocol that will detail how to handle metadata. The Parties anticipate that the ESI protocol will include an appendix that explicitly identifies each category of metadata that will be exchanged. The protocol will cover all the standard metadata fields, including custodians, modifiers, dates of creation

and modification, etc. Each piece of ESI exchanged will be accompanied by metadata.

If disputed, identify the nature of the dispute _____

- c. **Format.** Have the parties agreed on the format(s) for production of ESI?

☐ **Yes** ☐ No

The parties intend to file a stipulated ESI protocol that will detail the format for ESI production.

If no, what disputes remain outstanding ____

- d. **Clawback Agreement.** Will the parties be using the Form Inadvertent Production Provision of LCvR 16.1.D? ☐ **Yes** ☐ No

A Rule 502(d) Agreement was already submitted on the Master Docket for the SoClean MDL (ECF No. 63 in No. 22-mc-152) and the parties agree to be bound by it here.

If no, will an alternative provision be proposed? ☐ Yes (Please attach) ☐ No

- e. **Search terms.** Have the parties agreed on any protocol for review of electronic data? ☐ **Yes** ☐ No

If yes, please describe:

The Parties intend to file a stipulated ESI protocol that will detail how they will review electronic data for production. The Parties anticipate that the ESI protocol will provide for some flexibility in how the Parties will search for and review potentially-responsive material. The Parties anticipate that the ESI protocol will allow the parties to confer down the road if they believe TAR would be beneficial to making the productions more easily and quickly, but does not limit the means by how the producing party searches for and responds to ESI requests.

If no, please identify what issues remain outstanding _____

- f. **Accessibility.** Have the parties agreed on what ESI is "reasonably accessible" as defined in R. 26(b)(2)(B)? ☐ **Yes** ☐ **No**

The parties are conferring on this issue in connection with the ESI Protocol.

If no, please identify the nature of the dispute ____

- g. **Preservation.** Are there any unresolved issues pertaining to the preservation of ESI? If so, please describe _____

No, the parties are aware of their obligations, per PTO #1 and will outline them explicitly in the ESI Protocol.

- h. **Other.** Identify all outstanding issues or disputes concerning ESI _____

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12. **Set forth whether the parties have elected to schedule the Post-Discovery Status Conference following the completion of Fact Discovery or Expert Discovery; in either event the parties shall be prepared at the Post-Discovery Status Conference to discuss and/or schedule the following: (The parties are *not* required during their Rule 26(f) Conference to consider or propose dates for the items identified below. Those dates will be determined, if necessary, at the Post-Discovery Status Conference. Lead trial counsel for each party and each unrepresented party are required to attend the Post-Discovery Status Conference with their calendars in hand to discuss those items listed below that require scheduling. In addition, a representative with settlement authority of each party shall be required to attend; representatives with settlement authority of any insurance company providing any coverage shall be available throughout the Conference by telephone):**

The parties have elected to schedule the Post-Fact Discovery Dates, including expert discovery and class certification briefing, at the Post-Discovery Status Conference.

- a. **Settlement and/or transfer to an ADR procedure;**
- b. **Dates for the filing of expert reports and the completion of**

expert discovery as itemized in sub-paragraphs 9.f. through 9.k., above, if the parties elected to defer such discovery until after the Post-Discovery Status Conference;

- c. Dates by which dispositive motions pursuant to Fed. R. Civ. P. 56, replies thereto and responses to replies should be filed;**
 - d. Dates by which parties' pre-trial statements should be filed;**
 - e. Dates by which *in limine* and *Daubert* motions and responses thereto should be filed;**
 - f. Dates on which motions *in limine* and *Daubert* motions shall be heard;**
 - g. Dates proposed for final pre-trial conference;**
 - h. Presumptive and final trial dates.**
- 13. Set forth any other order(s) that the parties agree should be entered by the court pursuant to Fed. R. Civ. P. 16(b) or 26(c):**

Joint Statement:

Order Appointing Discovery Special Master (already entered)

Order Appointing Settlement Mediator (to be filed)

ESI Protocol (to be filed)

Protective Order (to be filed)

Privilege Log Protocol (to be filed)

Deposition Protocol (to be filed)

SoClean:

Order granting SoClean's Motion to Stay Discovery Pending SoClean's Motion to Dismiss the CAC (to be filed)

- 14. Set forth whether the parties anticipate that the court may have to appoint a special master to deal with any matter and if so, specify the proposed role of any such master and any special qualifications that such master may require to perform such role:**

Carole Katz has been appointed Discovery Special Master.

- 15. If the parties have failed to agree with regard to any subject for which a report is required as set forth above, except for proposed dates required in paragraph 9, above, briefly set forth the position of each party with regard to each matter on which agreement has not been reached:**

The Parties' positions on such disputed issues are set forth above.

- 16. Set forth whether the parties have considered the possibility of settlement of the action and describe briefly the nature of that consideration:**

The Parties intend to engage in settlement discussions facilitated by the appointment of a mediator, as discussed above.

AGREED TO AND STIPULATED TO BY:

SHARP LAW, LLP

/s/ Ruth Anne French-Hodson

Rex A. Sharp, KS #12350
Ruth Anne French-Hodson, KS #28492
Sarah T. Bradshaw, KS #26651
Sharp Law, LLP
4820 W. 75th St.
Prairie Village, KS 66208
Telephone: (913) 901-0505
Facsimile: (913) 901-0419
rsharp@midwest-law.com
rafrenchhodson@midwest-law.com
sbradshaw@midwest-law.com

and

MASON LLP

Gary E. Mason
Danielle L. Perry
5101 Wisconsin Ave., Suite 305
Washington, DC 20016
Tel: 202.429.2290
Fax: 202.429.2294
gmason@masonllp.com
dperry@masonllp.com

Co-lead Counsel for Consumer Plaintiffs

and

/s/ Gretchen E. Moore

Gretchen E. Moore
Pa. ID No. 202103
STRASSBURGER MCKENNA
GUTNICK & GEFSKY
Four Gateway Center, Suite 2200
444 Liberty Avenue
Pittsburgh, PA 15222
T - (412) 281-5423
gmoore@smgglaw.com

PROSKAUER ROSE LLP

/s/ Michael R. Hackett

Michael R. Hackett (MA BBO # 676693)
Proskauer Rose LLP
One International Place
Boston, MA 02110
p: 617-526-9600
f: 617-526-9899
mhackett@proskauer.com

Jeffrey H. Warshafsky
Proskauer Rose LLP
Eleven Times Square
New York, NY 10036
p: 212-969-3000
f: 212-969-2900
jwarshafsky@proskauer.com

Counsel for SoClean, Inc.

/s/ Daniel Bentz

Daniel R. Bentz (PA #200772)
Marks, O'Neill, O'Brien, Doherty & Kelly, P.C.
Suite 2600 Gulf Tower 707 Grant Street
Pittsburgh, PA 15219
Office: 412-391-6171
Direct: 412-467-2021
Fax: 412-391-8804
dbentz@moodklaw.com

Counsel for SoClean, Inc.